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[Continued on next page]

(54) Title: VESSEL CLOSURE DEVICES AND METHODS

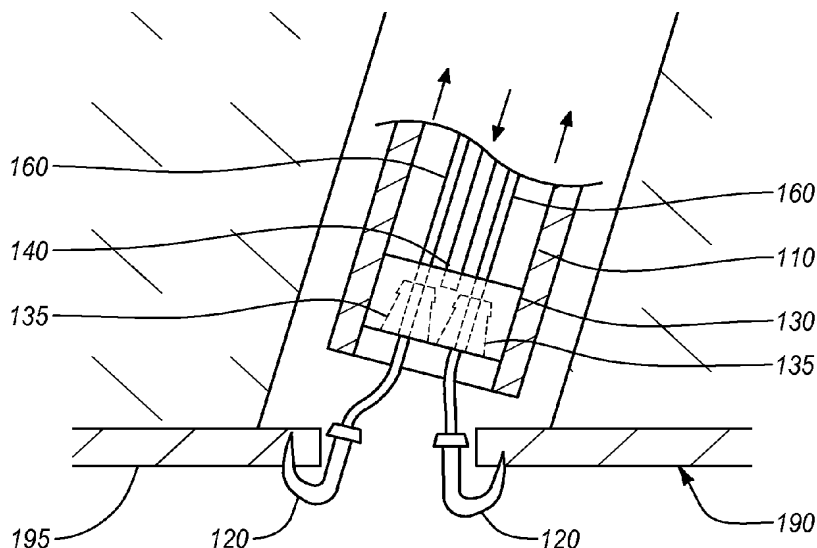


Fig. 2D

(57) Abstract: A closure device (100) configured for closing an opening in a body lumen. The closure device may include a delivery sheath (110), a cleat (130), and one or more anchors (120). The cleat may be disposed within and move longitudinally with respect to the delivery sheath. The one or more anchors may be configured to engage tissue surrounding the body lumen opening and selectively couple to the cleat to obstruct and/or close the body lumen opening.

Published:

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VESSEL CLOSURE DEVICES AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

This patent application claims priority to U.S. Patent Application Serial No. 12/684,562, entitled "Vessel Closure Devices and Methods," filed January 8, 2010, which claims the benefit of and priority to U.S. Provisional Patent Application Serial No. 61/143,751, entitled "Vessel Closure Devices and Methods," filed January 9, 2009, the disclosure of which is incorporated herein by reference in its entirety.

BACKGROUND

1. Technical Field

The present disclosure relates generally to medical devices and their methods of use. In particular, the present disclosure relates to vessel closure systems and devices and corresponding methods of use.

2. The Technology

Catheterization and interventional procedures, such as angioplasty or stenting, generally are performed by inserting a hollow needle through a patient's skin and tissue into the vascular system. A guidewire may be advanced through the needle and into the patient's blood vessel accessed by the needle. The needle is then removed, enabling an introducer sheath to be advanced over the guidewire into the vessel, e.g., in conjunction with or subsequent to a dilator.

A catheter or other device may then be advanced through a lumen of the introducer sheath and over the guidewire into a position for performing a medical procedure. Thus, the introducer sheath may facilitate introducing various devices into the vessel, while minimizing trauma to the vessel wall and/or minimizing blood loss during a procedure.

Upon completing the procedure, the devices and introducer sheath would be removed, leaving a puncture site in the vessel wall. Traditionally, external pressure would be applied to the puncture site until clotting and wound sealing occur; however, the patient must remain bedridden for a substantial period after clotting to ensure closure of the wound. This procedure may also be time consuming and expensive, requiring as much as an hour of a physician's or nurse's time. It is also uncomfortable for the patient and requires that the patient remain immobilized in the operating room, catheter lab, or holding area. In addition, a risk of hematoma exists from bleeding before hemostasis

occurs. Although some closure systems may be available, they provide limited control to flexibility to the operator, which may lead to improper or undesirable closure of the puncture site.

5

BRIEF SUMMARY

The present disclosure includes a closure device. In one embodiment, the closure device is configured for closing an opening in a body lumen comprising. The closure device can include a delivery sheath, a cleat, and one or more anchors. In addition, the cleat can be configured to be disposed within and move longitudinally with respect to the delivery sheath. In a further embodiment, the one or more anchors can be configured to
10 engage tissue surrounding the body lumen opening and couple with the cleat.

The present disclosure also includes a method of closing an opening in a body lumen. In one embodiment, the method can include advancing a closure device at least partially into the body lumen opening. The closure device can include a delivery sheath,
15 a cleat disposed within the delivery sheath, and one or more anchors disposed within the delivery sheath distal of the cleat. The method may also include deploying the one or more anchors from a distal end of the delivery sheath. In further embodiments, the method can include engaging a distal surface of the body lumen with the one or more anchors.

20 These and other advantages and features of the present disclosure will become more fully apparent from the following description and appended claims, or may be learned by the practice of the disclosure as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

25 To further clarify the above and other advantages and features of the present disclosure, a more particular description will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It is appreciated that these drawings depict only illustrated embodiments and are therefore not to be considered limiting of its scope. The disclosure will be described and explained with
30 additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 illustrates an example closure device in accordance with an embodiment of the present disclosure.

Figures 2A-2F illustrate an example deployment of the closure device of Figure 1.

DETAILED DESCRIPTION

The present disclosure relates to devices, systems, and methods for closing an opening in a body lumen. The devices, systems, and methods of this disclosure may have a variety of benefits over those previously available. In particular, the devices, systems, and methods of this disclosure may assist a medical care provider to quickly and efficiently close a body lumen opening after a percutaneous procedure without many of the risks and inefficiencies associated with traditional body lumen closure methods and devices.

Reference is now made to Figure 1, which illustrates an example closure device 100 in accordance with the present disclosure. The closure device 100 may be configured for operation by a medical care provider to close an opening in a body lumen, such as after a percutaneous medical procedure.

In one embodiment, the closure device 100 may include a delivery sheath 110, a cleat 130 housed within the delivery sheath 110, a mandrel 140 coupled to the cleat 130, two elongate members 160 disposed within the delivery sheath 110 and through the cleat 130, and anchors 120, such as hooks, respectively coupled to the distal ends of the elongate members 160. In operation, a medical care provider may utilize the closure device 100 to close a body lumen opening. For example, the medical care provider may engage and/or stabilize the tissue surrounding a body lumen opening with the anchors 120 and then close the body lumen opening using the cleat to pull the anchors 120 together and obstruct the opening, as will be described in more detail below.

As mentioned above, the closure device 100 may include a delivery sheath 110. The delivery sheath 110 may be configured to house, protect, and/or deliver one or more other components of the delivery device. For example, the delivery sheath 110 may at least partially house the anchors 120, cleat 130, mandrel 140, and/or elongate members 160. As a result, a medical care provider can deliver the components of the closure device 100 near or into a body lumen opening through movement and manipulation of the delivery sheath 110.

The delivery sheath 110 may have any number of mechanical properties as desired for a particular application. For example, the delivery sheath 110 may have any level of flexibility or rigidity desired. In one embodiment, the delivery sheath 110 may be rigid, semi-rigid, or flexible. In further embodiments, the delivery sheath 110 may have different mechanical properties along the length thereof. For example, the delivery sheath 110 may have a substantially rigid proximal portion to facilitate manipulation by a

medical care provider and a more flexible distal portion to facilitate entry into and maneuverability within a body lumen.

The delivery sheath 110 may include any of a number of different materials. For example, the delivery sheath 110 may include one or more polymers or metals. In one embodiment, the delivery sheath 110 may include biocompatible plastic. In further
5 embodiments, the delivery sheath may comprise any number or combination of biocompatible materials.

In one embodiment, the delivery sheath 110 may be generally tubular along its length. In addition, the delivery sheath 110 may have any size desired for a particular application. For example, the delivery sheath 110 may have the size of a typical tissue
10 tract and/or body lumen opening associated with percutaneous medical procedures. In one embodiment, the delivery sheath 110 may have a diameter of about 5 french to about 15 french. In further embodiments, the delivery sheath 110 may have a diameter of approximately 6 french or 12 french.

In addition to the delivery sheath 110, the closure device 100 may include a cleat
15 130. The cleat 130 may be initially housed within the delivery sheath 110 and configured to be deployed to assist in closing a body lumen opening. The cleat 130 may be slidable relative to the delivery sheath 110 to facilitate relative movement between the cleat 130 and the other components of the closure device 100.

In one embodiment, the cleat 130 may have a generally cylindrical outer shape. In further embodiments, the cleat 130 may have any shape desired or suitable for obstructing
20 a body lumen opening. The size of the cleat 130 may also vary as desired for a particular application, depending on the size of the body lumen opening to be closed or other considerations.

The cleat 130 may include any of a number or combination of different materials. In one embodiment, the cleat 130 may include a bioabsorbable plastic. In further
25 embodiments, the cleat 130 may include any biocompatible, bioresorbable, bioabsorbable, and bioerodible materials, or combinations thereof.

The cleat 130 may also include one or more recesses 135 configured to receive the
30 anchors 120 and/or allow the elongate members 160 to pass through the cleat 130. In one embodiment, the recesses 135 of the cleat 130 may be configured to lock the anchors 120 in place when the recesses 135 receive the anchors 120. For example, the anchors 120 may lock into the recesses 135 with a snap-fit configuration. In further embodiments, the anchors 120 may lock into the recesses with any other suitable mechanism, such as

threading, pinning, or bonding. As a result, once the anchors 120 lock into the recesses 135, the resulting combination may close the body lumen opening by obstructing the opening and/or locking the tissue surrounding the opening in place. In further embodiments, the recesses 135 may have flared distal openings to facilitate receipt of the anchors 120. The number of recesses 135 may vary as desired and/or in conjunction with the number of anchors 120 and elongate members 160. For example, the cleat may have one, two, three, four, or more recesses 120. In further embodiments, the cleat 130 may have an additional opening configured to allow passage of a guidewire so that the closure device 100 may operate in an over-the-wire configuration.

The closure device 100 may also include a mandrel 140 coupled to the cleat 130. In one embodiment, the mandrel 140 may be configured to allow a medical care provider to manipulate the mandrel 140 in order to advance or retract the cleat 130 as desired. In addition, the mandrel 140 may move independent of the delivery sheath 110 in order to facilitate relative movement between the delivery sheath 110 and the cleat 130.

In further embodiments, the mandrel 140 may couple to the cleat 130 in a manner that allows the mandrel 140 to disengage the cleat 130 once the cleat is deployed. For example, the mandrel 140 may be selectively removable from the cleat 130 such that a medical care provider may uncouple the mandrel 140 from the cleat 130 and remove the mandrel 140 from the tissue tract after the cleat 130 is deployed. In one embodiment, the mandrel 140 may be threaded into the cleat 130 or otherwise removably coupled to the cleat 130.

The mandrel 140 may have any of a variety of mechanical properties and physical configurations. In one example, the mandrel may be substantially rigid. However, in further embodiments, the mandrel 140 may have any level of rigidity or flexibility desired for a particular application. In addition, in one embodiment, the mandrel 140 may be generally tubular and/or hollow. In further embodiments, the mandrel 140 may have a solid cross section.

The mandrel 140 may include any of a number of different materials. For example, the mandrel 140 may include any number or combination of metals or polymers. In one embodiment, the mandrel 140 may be a hollow metal shank. In further embodiments, the mandrel 140 may include one or more plastics.

In addition to a mandrel 140, the closure device may include anchors 120. The anchors 120 may be disposed distal of the cleat 130 and may be configured to grip and/or engage the tissue surrounding a body lumen opening. In one embodiment, the anchors

120 may have a hook-like configuration. However, in further embodiments, the anchors 120 may have any configuration suitable for engaging and/or stabilizing the body lumen tissue. In one embodiment, the anchors 120 may be configured to pierce the inner surface of a lumen wall. In further embodiments, the anchors 120 may be configured to engage
5 the outer surface of the lumen wall or a combination of the inner and outer surfaces of the lumen wall. In yet further embodiments, the anchors 120 may include any number of tissues engaging features, such as hooks, ridges, teeth, and/or similar structures.

The number of anchors 120 can vary as desired for a particular application. For example, although the closure device 100 is illustrated having two anchors 120, in further
10 embodiments, the closure device 100 may have a single anchor or three, four, or more anchors. As disclosed above, the anchors 120 may also be configured to engage and lock into the recesses 135 of the cleat 130. For example, portions of the anchors 120 may have a shape corresponding to the shapes of the recesses 135 to facilitate engagement between the anchors 120 and the recesses 135.

15 In one embodiment, each anchor 120 may have a hook portion 120a and a collar portion 120b. The hook portion 120a may be configured to engage and/or pierce tissue. The hook portion 120a may include any number of points, barbs, ridges, teeth, and/or other projections. In further embodiments, each anchor 120 may include a plurality of hook portions 120a, such as two, three, four, or more hook portions 120a. The collar
20 portion 120b may be configured to snap into a correspondingly-shaped portion of a recess 135. In yet further embodiments, the collar portion 120b may have any size or shape desired or suitable for a particular application.

The anchors 120 may be positioned to engage the tissue surrounding an opening in a body lumen. In particular, the anchors 120 may be positioned such that the hook
25 portions 120a are pointed radially outwardly. In addition, the anchors 120 may be configured to move radially outwardly once deployed from the delivery sheath 110 such that the hook portions 120a of the anchors 120 are in a position to engage the tissue surrounding the body lumen opening. For example, the elongate members 160 may be configured to move the anchors 120 into a deployed configuration once the anchors 120
30 are advanced out of the delivery sheath 110, as will be explained in more detail below.

The anchors 120 may include any number of different materials or combinations thereof. For example, the anchors 120 may include any number of biocompatible metals or polymers. In one embodiment, the anchors 120 may include one or more bioabsorbable plastics. In further embodiments, the anchors 120 may include any

biocompatible, bioresorbable, bioabsorbable, or bioerodible materials, or combinations thereof.

In addition to anchors 120, the closure device 100 may include one or more elongate members 160 extending within the delivery sheath 110, through the recesses of the cleat 130, and coupled at a distal end to the anchors 120. The elongate members 160 may be configured to assist a medical care provider to deploy the closure device 100. For example, a medical care provider may use the elongate members 160 to advance the anchors 120 from the delivery sheath 110 and then engage tissue surrounding a body lumen opening with the anchors 120.

The elongate members 160 may have any of a variety of physical or mechanical properties desired for a particular application. For example, the elongate members 160 may have any level of flexibility or rigidity. In one embodiment, the elongate members 160 may be substantially rigid, semi-rigid, or flexible. The elongate members 160 may have a solid circular or hollow tubular cross-section. In further embodiments, the elongate members 160 may be wires. In yet further embodiments, the elongate members 160 may have shape-memory or superelastic characteristics to assist in deploying the anchors 120. In additional embodiments, the elongate members 160 may be configured to resist twisting in order to ensure proper positioning and direction of the anchors 120.

In one embodiment, the elongate members 160 may couple at a proximal end to a mechanism, such as a plunger, configured to allow a medical care provider to advance or retract the elongate members 160 relative to the delivery sheath 110. As a result, the plunger may facilitate deployment of the anchors 120 and prevent relative longitudinal movement between the anchors 120.

The elongate members 160 may have any of a variety of different materials. In one embodiment, the elongate members 160 may include material made from any of a variety of known suitable materials, such as a shape memory material (SMM). SMMs have a shape memory effect in which they can be made to remember a particular shape. Once a shape has been remembered, the SMM can be bent out of shape or deformed and then returned to its original shape by unloading from strain or heating. Typically, SMMs can be shape memory alloys (SMA) comprised of metal alloys, or shape memory plastics (SMP) comprised of polymers. The materials can also be referred to as being superelastic.

Usually, an SMA can have any non-characteristic initial shape that can then be configured into a memory shape by heating the SMA and conforming the SMA into the

desired memory shape. After the SMA is cooled, the desired memory shape can be retained. This allows for the SMA to be bent, straightened, compacted, and placed into various contortions by the application of requisite forces; however, after the forces are released, the SMA can be capable of returning to the memory shape. The SMAs used
5 may include the following: copper-zinc-aluminum; copper-aluminum-nickel; nickel-titanium (NiTi) alloys known as nitinol; and cobalt-chromium-nickel; nickel-titanium platinum; nickel-titanium palladium or cobalt-chromium-nickel-molybdenum alloys known as elgiloy alloys.

For example, the elongate members 160 may include NiTi alloy that forms
10 superelastic nitinol. In the present case, the nitinol materials can be trained to remember a certain shape, such as a straightened shaft. Thereafter, the elongate members 160 may be bent or otherwise deflected away from the memory shape and then return to the memory shape once released. In one embodiment, the elongate members 160 may have a straight memory shape. In further embodiments, the elongate members 160 may be
15 deflected in order to position the elongate members 160 and anchors 120 within the delivery sheath 110 in a delivery configuration, as shown in Figure 1. Once the elongate members 160 are advanced in a distal direction relative to the delivery sheath 110 and the anchors 120 deployed from the distal end of the delivery sheath 110, the elongate members 160 may return to their memory shape and move the anchors 120 into position
20 to engage the tissue surrounding the body lumen opening.

Reference is now made to Figures 2A-2F, which disclose various steps of deploying the closure device 100 to close an opening in a body lumen 190. As shown in Figure 2A, the closure device 100 can be advanced into a body lumen 190 by advancing the delivery sheath 110 through the opening in the lumen wall 195. A medical care
25 provider may accomplish this by advancing the closure device 100 over a guidewire or by advancing the closure device 100 through an introducer sheath. Once the distal end of the delivery sheath 100 is positioned within the body lumen 190, the medical care provider may deploy the anchors 120 by advancing the elongate members 160 in a distal direction relative to the delivery sheath 110, as shown in Figure 2B. Once deployed, the anchors
30 120 and elongate members 160 may relax to their open or memory position and extend radially outwardly beyond the walls of the delivery sheath 110.

Thereafter, the medical care provider may retract the closure device 100 in a proximal direction, thereby partially withdrawing the closure device 100 from the body lumen 190, as shown in Figure 2C. The medical care provider may continue to retract the

closure device 100 until the anchors 120 engage tissue near the opening in the body lumen 190, thereby anchoring into the lumen wall 195. Once the anchors 120 engage the tissue surrounding the opening in the lumen wall 195, the medical care provider may advance the cleat 130 in a distal direction relative to the anchors 120 and delivery sheath 110. For example, the medical care provider may retain the delivery sheath 110 and anchors 120 in position while advancing the mandrel 140 in a distal direction to advance the cleat 130. As the cleat 130 advances in a distal direction, it may draw or pull the anchors 120 radially inward, thereby also pulling the anchored tissue together.

As shown in Figure 2E, the cleat 130 may advance into engagement with the anchors 120. In one embodiment, the anchors 120 may snap fit into the recesses 135 of the cleat 130, thereby locking the cleat 130, anchors 120, and anchored tissue in place. As a result, the opening may be closed by bringing the tissue surrounding the opening together and/or by obstructing the opening with the cleat 130. Once closure is achieved, the delivery sheath 110, mandrel 140, and elongate members 160 may be retracted, thereby leaving the cleat 130 and anchors 120 in place. In one embodiment, the mandrel 140 and elongate members 160 may be uncoupled from the cleat 130 and anchors 120, respectively. In further embodiments, the elongate members 160 may be trimmed to facilitate retraction of the elongate members 160.

The present disclosure may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the disclosure is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS

We claim:

1. A closure device for closing an opening in a body lumen comprising:
5 a delivery sheath;
a cleat configured to be disposed within and move longitudinally with respect to the delivery sheath; and
one or more anchors configured to engage tissue surrounding the body lumen opening and couple with the cleat.
10
2. The closure device of claim 2, further comprising the cleat having one or more recesses configured to receive the one or more anchors.
3. The closure device of claim 3, further comprising the one or more recesses and
15 one or more anchors being configured to lock together.
4. The closure device of claim 4, further comprising the one or more anchors being configured to lock into the one or more recesses with a snap-fit configuration.
- 20 5. The closure device of claim 1, further comprising one or more elongate members coupled at a distal end to the one or more anchors and configured to pass through and be slidable relative to the cleat.
6. The closure device of claim 5, wherein the one or more elongate members
25 comprise superelastic wires.
7. The closure device of claim 1, further comprising a mandrel being configured to selectively couple to the cleat.
- 30 8. The closure device of claim 7, wherein the mandrel comprises a hollow metal shank.
9. The closure device of claim 1, wherein the cleat comprises bioabsorbable plastic.

10. The closure device of claim 1, wherein the one or more anchors comprise bioabsorbable plastic.

5 11. The closure device of claim 1, wherein each anchor comprises a hook portion configured to engage tissue and a collar portion configured to couple with the cleat.

12. The closure device of claim 1, wherein the recesses include flared distal openings.

13. A method of closing an opening in a body lumen comprising:
advancing a closure device at least partially into the body lumen opening, the
closure device comprising:

5 a delivery sheath;
 a cleat disposed within the delivery sheath; and
 one or more anchors disposed within the delivery sheath distal of the cleat;
deploying the one or more anchors from a distal end of the delivery sheath; and
engaging a distal surface of the body lumen with the one or more anchors.

10 14. The method of claim 13, further comprising advancing the cleat in a distal
direction over one or more elongate members coupled at a distal end to the one or more
anchors to pull the anchors and engaged tissue together.

15 15. The method of claim 14, wherein advancing the cleat in a distal direction
comprises advancing a mandrel coupled to the cleat in a distal direction relative to the one
or more elongate members and one or more anchors.

20 16. The method of claim 15, further comprising locking the anchors into
correspondingly-shaped recesses within the cleat.

 17. The method of claim 16, further comprising uncoupling the mandrel from the
cleat.

25 18. The method of claim 17, further comprising trimming the elongate members
proximal of the cleat.

 19. The method of claim 18, further comprising retracting the delivery sheath, one
or more elongate members, and mandrel away from the body lumen.

30 20. The method of claim 19, wherein the one or more elongate members comprise
super elastic wires, the cleat comprises bioabsorbable plastic, and the one or more
anchors comprise bioabsorbable plastic.

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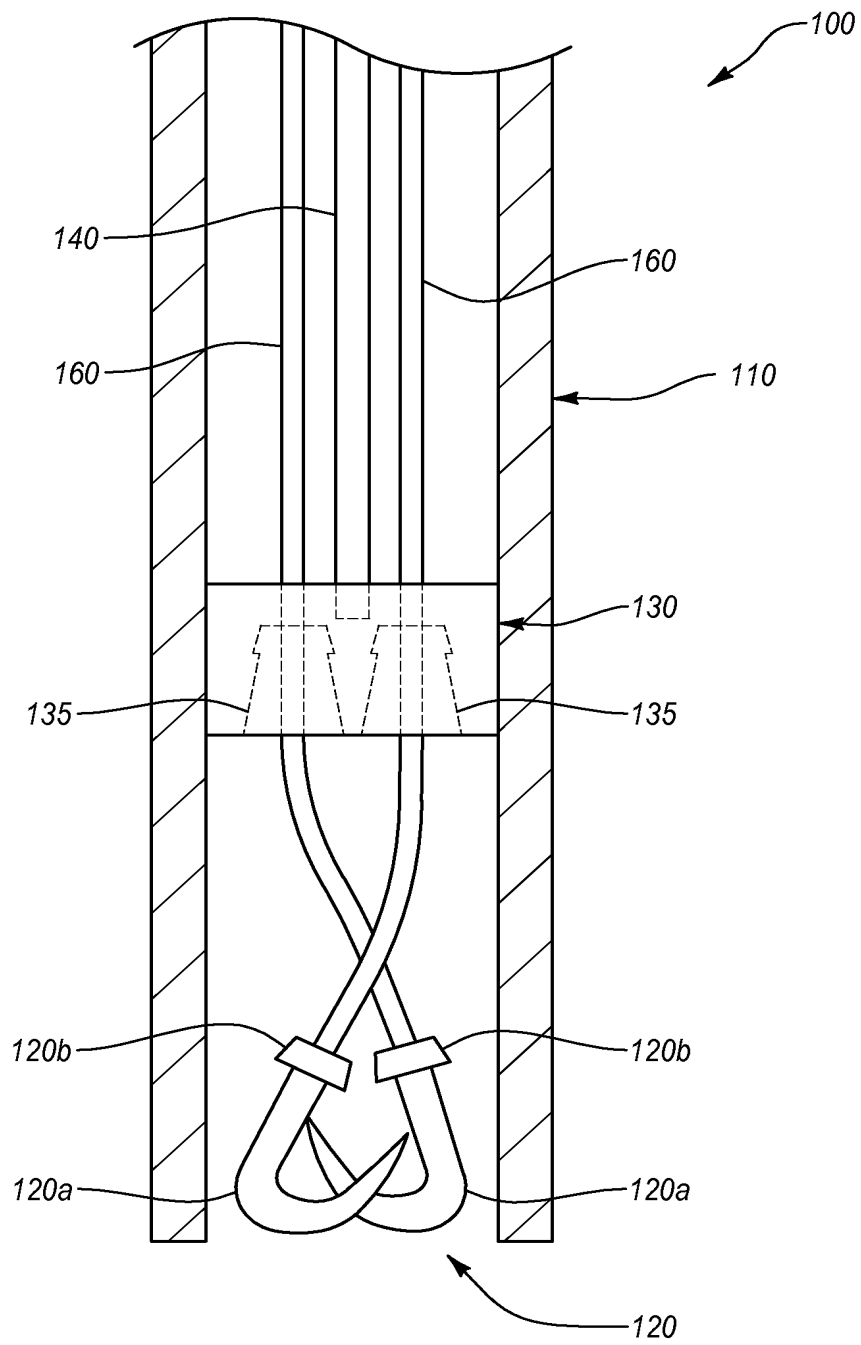


Fig. 1

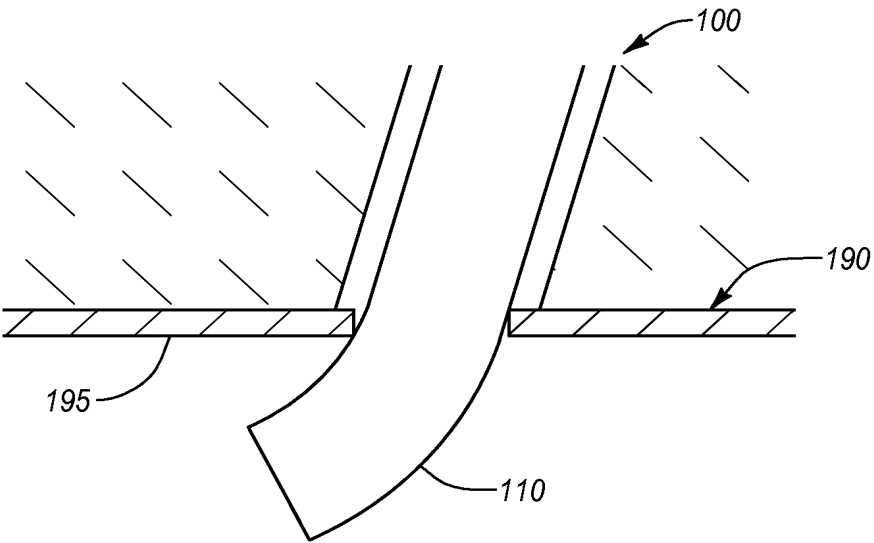


Fig. 2A

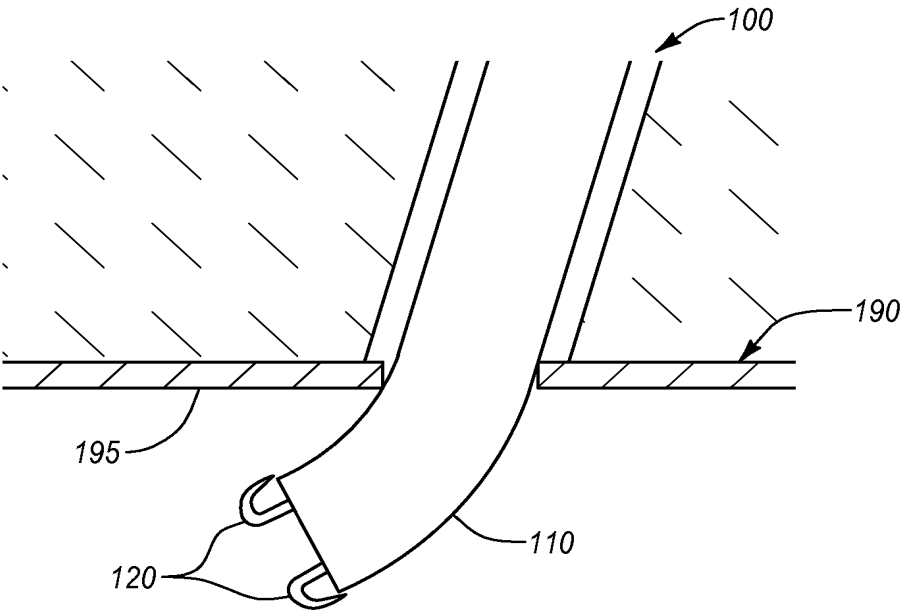


Fig. 2B

3 / 4

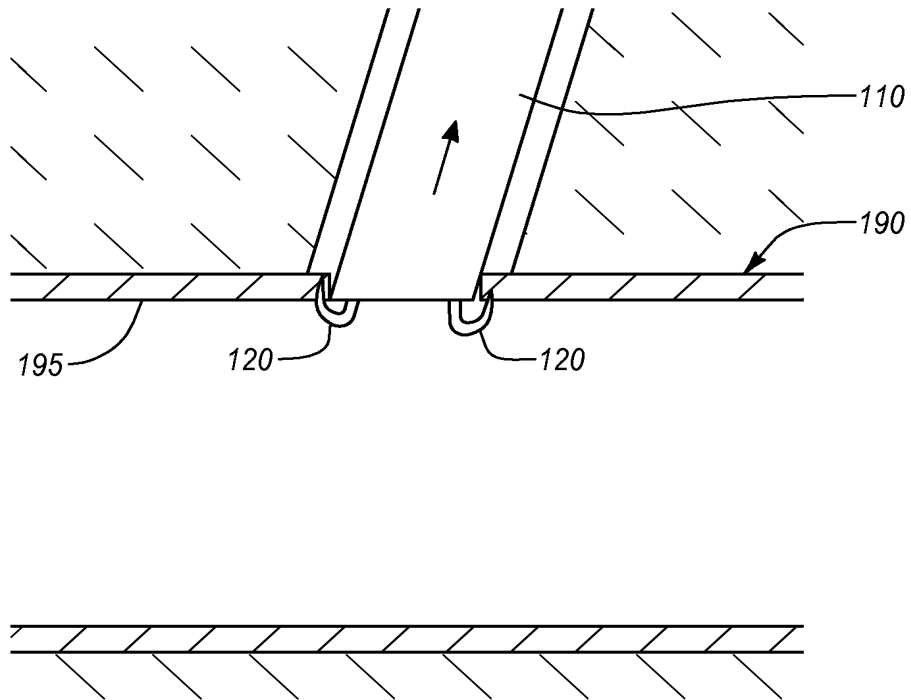


Fig. 2C

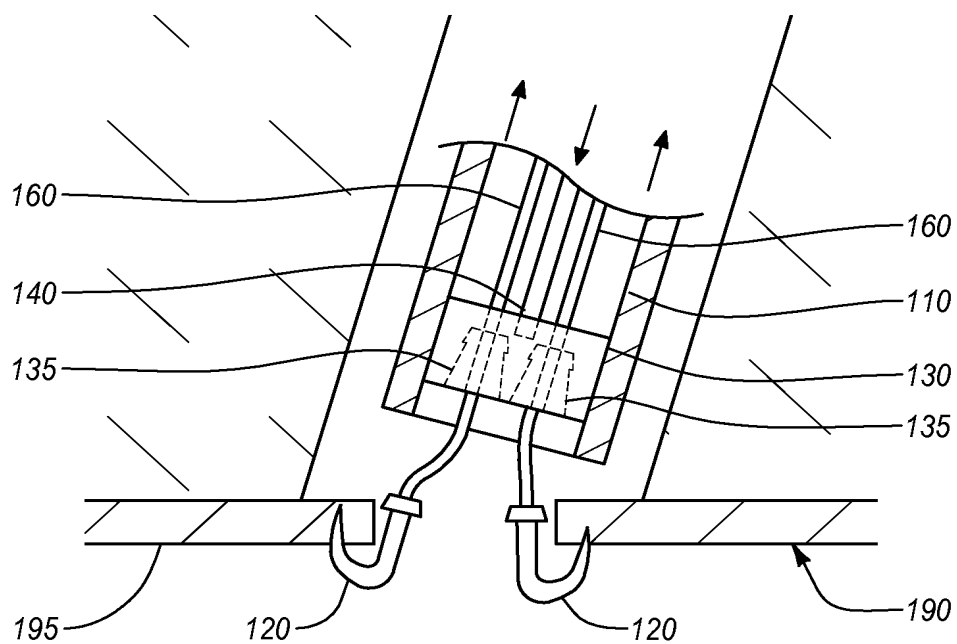


Fig. 2D

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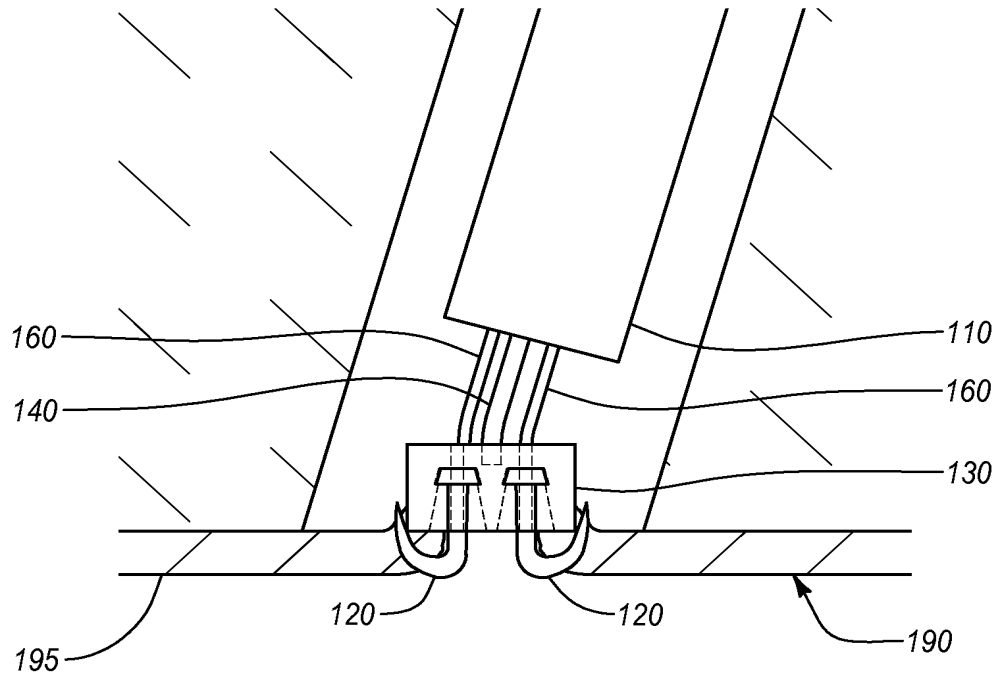


Fig. 2E

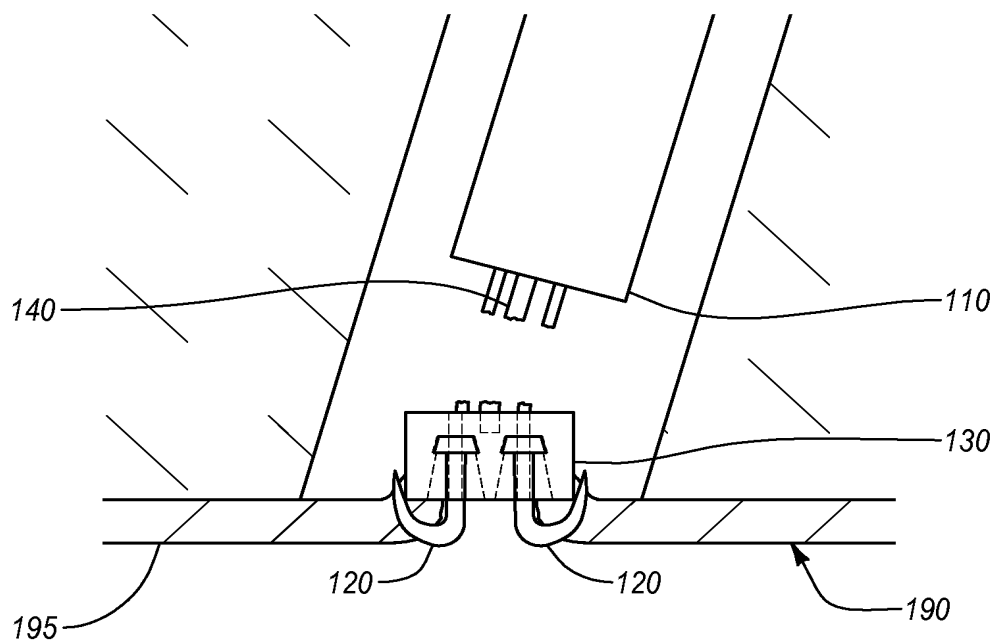


Fig. 2F

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/020661

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00 A61B17/064
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | US 6 860 895 B1 (AKERFELDT DAN [SE] ET AL) 1 March 2005 (2005-03-01) figures 1-7 column 3, line 55 - line 58 ----- | 1-10,12 |
| X | US 2004/249412 A1 (SNOW BRENT W [US] ET AL) 9 December 2004 (2004-12-09) figures 6,7 ----- | 1-3,6-11 |
| X | DE 10 2006 056283 A1 (BIOMAGNETIK PARK GMBH [DE]) 5 June 2008 (2008-06-05) figures 3-7 ----- | 1-3,7,8, 11 |
| X | US 7 311 720 B2 (MUELLER GOTTFRIED [DE] ET AL) 25 December 2007 (2007-12-25) figures 1-6 ----- | 1-5,7,8 |

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search

14 April 2010

Date of mailing of the international search report

23/04/2010

Name and mailing address of the ISA/
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Authorized officer

Schießl, Werner

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/020661

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 13-20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2010/020661

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